Notice of Allowability	Application No.	Applicant(s)	
	09/299,139	BROWNING ET AL.	
	Examiner	Art Unit	
	Christopher H. Yaen	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 7/10/2006.

2. ☒ The allowed claim(s) is/are 51,53,55,56,71,75,77,78,84,86,88,89,95-98,100,102-104,106,108-112,114 and 116-123.

3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date 12/15/2005
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

CHRISTOPHER H. YAEN
PRIMARY EXAMINER

Christopher Yaen
Art Unit 1643

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Amy Mandragouras on 9/26/2006.

The application has been amended as follows:

1-50. (Canceled).

51. (Previously presented) A method for inhibiting a humoral immune response in a human comprising administering to the human mammal a pharmaceutical composition comprising an effective amount of a soluble human lymphotoxin-beta receptor (LTβR) fused to one or more heterologous protein domains, wherein the soluble human LTβR comprises at least one ligand binding domain that can selectively bind to a human surface LT ligand, and a pharmaceutically acceptable carrier, such that a humoral immune response is inhibited.

52. (Canceled)

53. (Previously presented) The method according to claim 51, wherein the ligand binding domain comprises SEQ ID NO: 1, or a functional fragment thereof encoding an LTβR ligand binding domain.

54. (Canceled)

55. (Previously presented) The method according to claim 51, wherein the heterologous protein domain is selected from the group consisting of immunoglobulins, serum albumin, lipoproteins, apolipoproteins, and transferrin.

56. (Previously Presented) The method according to claim 51, wherein the heterologous protein domain comprises a human immunoglobulin Fc domain.

57-70. (Canceled)

71. (Previously presented) A method for inhibiting a humoral immune response by inhibiting LT-β receptor signaling without inhibiting TNF-R signaling in a human subject comprising administering to a human subject a pharmaceutical composition comprising an amount of a soluble human lymphotoxin-β receptor (LTβR) fused to one or more heterologous protein domains, wherein the soluble human LTβR comprises at least one ligand binding domain that can selectively bind to a human surface LT ligand, and a pharmaceutically acceptable carrier, such that a humoral immune response is inhibited by inhibiting human LT-β receptor signaling without inhibiting TNF-R signaling.

72-74. (Canceled)

75. (Previously presented) The method according to claim 71, wherein the ligand binding domain comprises SEQ ID NO: 1, or a functional fragment thereof encoding an LTβR ligand binding domain.

76. (Canceled)

78. (Previously presented) The method according to claim 71, wherein the heterologous protein domain comprises a human immunoglobulin Fc domain.

79-83. (Canceled)

84. (Previously presented) A method for disrupting the association of immune complexes and B cell follicles in a human subject comprising administering to the human subject a pharmaceutical composition comprising an amount of a soluble human lymphotoxin-β receptor (LTβR) fused to one or more heterologous protein domains, wherein the soluble human LTβR comprises at least one ligand binding domain that can selectively bind to a human surface LT ligand, and pharmaceutically acceptable carrier, such that the association of immune complexes and B cell follicles is disrupted.

85. (Canceled)

86. (Previously presented) The method according to claim 84, wherein the ligand binding domain comprises SEQ ID NO: 1, or a functional fragment thereof encoding an LTβR ligand binding domain.

87. (Canceled)

88. (Previously presented) The method according claim 84, wherein the heterologous protein domain is selected from the group consisting of immunoglobulins, serum albumin, lipoproteins, apolipoproteins and transferfin.

89. (Previously presented) The method according to claim 84, wherein the heterologous protein domain comprises a human immunoglobulin Fc domain.

90-94. (Canceled)

95. (Previously presented) A method of treating an antibody-mediated autoimmune disorder in a human subject suffering from an autoimmune disorder, comprising administering to the human subject a pharmaceutical composition comprising an effective amount of a soluble human lymphotoxin- β receptor (LTβR) fused to one or more heterologous protein domains, wherein the soluble human LTβR comprises at least one ligand binding domain that can selectively bind to a human surface LT ligand, and a pharmaceutically acceptable carrier, such that the antibody-mediated autoimmune disorder is treated.

96. (Previously presented) The method of claim 95, wherein the autoimmune disorder is selected from the group consisting of Myasthenia gravis, autoimmune hemolytic anemia, idiopathic thrombocytopenia purpura (ITP), systemic lupus erythematosus (SLE), Wegener's granulomatosis, poly-arteritis nodosa, and rapidly progressive crescentic glomerulonephritis.

97. (Previously presented) The method of claim 95, wherein the autoimmune disorder is a chronic inflammatory disease.

98. (Previously presented) The method of claim 97, wherein the chronic inflammatory disease is Chagas' disease or Grave's disease.

99. (Canceled)

100. (Previously presented) The method according to claim 95, wherein the ligand binding domain comprises SEQ ID NO: 1, or a functional fragment thereof encoding an LTβR ligand binding domain.

101. (Canceled)

100. (Previously presented) The method according to claim 95, wherein the ligand binding domain comprises SEQ ID NO: 1, or a functional fragment thereof encoding an LTβR ligand binding domain.

101. (Canceled)

102. (Previously presented) The method according to claim 95, wherein the heterologous protein domain is selected from the group consisting of immunoglobulins, serum albumin, lipoproteins, apolipoproteins, and transferrin.

103. (Previously presented) The method according to claim 95, wherein the heterologous protein domain comprises a human immunoglobulin Fc domain.

104. (Previously presented) A method of inhibiting a humoral response in a human subject suffering from a hypersensitivity response, comprising administering to the human subject a pharmaceutical composition comprising an effective amount of a soluble human lymphotoxin- β receptor (LTβR) fused to one or more heterologous protein domains, wherein the soluble human LTβR comprises at least one ligand binding domain that can selectively bind to a human surface LT ligand, and a pharmaceutically acceptable carrier, such that a humoral response is inhibited.

105. (Canceled)

106. (Previously presented) The method according to claim 104, wherein the ligand binding domain comprises SEQ ID NO: 1, or a functional fragment thereof encoding an LTβR ligand binding domain.

107. (Canceled)

108. (Previously presented)The method according to claim 104, wherein the

110. (Previously presented) The method of claim 104, wherein the hypersensitivity response is a type I response.

111. (Previously presented) The method of claim 104, wherein the hypersensitivity response is a type II or type III response.

112. (Previously presented) A method of inhibiting a humoral response associated with graft rejection in a human subject comprising administering a pharmaceutical composition comprising an effective amount of a soluble human lymphotoxin-β receptor (LTβR) fused to one or more heterologous protein domains, wherein the soluble human LTβR comprises at least one ligand binding domain that can selectively bind to a human surface LT ligand, and a pharmaceutically acceptable carrier, such that the humoral immune response associated with graft rejection is inhibited.

113. (Canceled)

114. (Previously presented) The method according to claim 112, wherein the ligand binding domain comprises SEQ ID NO: 1, or a functional fragment thereof encoding an LTβR ligand binding domain.

115. (Canceled)

116. (Previously presented) The method according to claim 112, wherein the heterologous protein domain is selected from the group consisting of immunoglobulins, serum albumin, lipoproteins, apolipoproteins, and transferrin.

117. (Previously presented) The method according to claim 112, wherein the heterologous protein domain comprises a human immunoglobulin Fc domain.

116. (Previously presented) The method according to claim 112, wherein the heterologous protein domain is selected from the group consisting of immunoglobulins, serum albumin, lipoproteins, apolipoproteins, and transferrin.

117. (Previously presented) The method according to claim 112, wherein the heterologous protein domain comprises a human immunoglobulin Fc domain.

118. (Currently amended) The method according to claim ~~any of claims~~ 51, ~~71 or 84,~~ wherein the soluble human lymphotoxin- β receptor (LTβR) comprises SEQ ID NO: 1.

119. (Previously presented) A method for inhibiting a humoral immune response in a human comprising administering a pharmaceutical composition comprising a soluble human lymphotoxin-beta receptor (LTβR) comprising SEQ ID NO: 1 fused to a human IgG1 Fc domain and a pharmaceutically acceptable carrier, such that the humoral immune response is inhibited.

120. (Previously presented) A method for inhibiting a humoral immune response by inhibiting LT- β receptor signaling without inhibiting TNF-R signaling in a human comprising administering a pharmaceutical composition comprising a soluble human lymphotoxin-beta receptor (LTβR) comprising SEQ ID NO: 1 fused to a human IgG1 Fc domain and a pharmaceutically acceptable carrier, such that the humoral immune response is inhibited by inhibiting human LT- β receptor signaling without inhibiting TNF-R signaling.

121. (Previously presented) A method for disrupting the association of immune complexes and B cell follicles in a human comprising administering a

pharmaceutical composition comprising a soluble human lymphotoxin-beta receptor (LTβR) comprising SEQ ID NO: 1 fused to a human IgG1 Fc domain and a pharmaceutically acceptable carrier, such that the association of immune complexes and B cell follicles is disrupted.

122. (New) The method according to claim 71 wherein the soluble human lymphotoxin- β receptor (LTβR) comprises SEQ ID NO: 1.

123. (New) The method according to claim 84 wherein the soluble human lymphotoxin- β receptor (LTβR) comprises SEQ ID NO: 1.

All rejections and or objections are withdrawn in view of the applicant's amendments and arguments thereto as set forth in 7/10/2006

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H. Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christopher Yaen
Art Unit 1643
September 28, 2006

CHRISTOPHER H. YAEN
PRIMARY EXAMINER